

ADOPTED: 4 July 2017

doi: 10.2903/j.efsa.2017.4961

Assessment of a decontamination process for dioxins and dioxin-like PCBs in fish oil by physical filtration with activated carbon

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Abstract

Following a request from the European Commission, the EFSA Panel on Contaminants in the Food Chain (CONTAM) provided a scientific opinion on the assessment of a decontamination process consisting in the adsorption with activated carbon and physical filtration of fish oil in order to reduce the amount of dioxins (polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)) and dioxin-like polychlorinated biphenyls (DL-PCBs). All feed decontamination processes must comply with the acceptability criteria specified in the Commission Regulation (EU) 2015/786. The data provided by the feed business operator were assessed with respect to the efficacy of the process and on information demonstrating that the process does not adversely affect the characteristics and the nature of the product. As described in scientific literature, the process was effective in removing PCDD/Fs (84%) and DL-PCBs (55%), and therefore, it is possible to meet the current EU requirements with respect to these contaminants, assuming that the level of contamination of untreated fish oil was within the range of the tested batches. The Panel considered that the reference to information available in published literature was a pragmatic approach to demonstrate that the use of activated carbon adsorption does not lead to any detrimental changes in the nature of the fish oil; however, it was noted that the process could deplete some beneficial constituents (e.g. vitamins). Information was provided to demonstrate the safe disposal of the waste material. The CONTAM Panel concluded that on the basis of the information submitted by the feed business operator the proposed decontamination process to remove dioxins (PCDD/Fs) and DL-PCBs from the fish oil by means of physical filtration with activated carbon, was compliant with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

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Keywords: decontamination process, feed, dioxins, PCDD/Fs, dioxin-like PCBs, fish oil, physical filtration

Requestor: European Commission

Question number: EFSA-Q-2016-00794

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Suggested citation: EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Knutsen HK, Alexander J, Barregård L, Bignami M, Bruschweiler B, Ceccatelli S, Cottrill B, Dinovi M, Edler L, Grasl-Kraupp B, Hoogenboom LR, Nebbia CS, Oswald IP, Petersen A, Rose M, Roudot A-C, Schwerdtle T, Vleminckx C, Vollmer G, Wallace H, Lundebye A-K, Metzler M, Colombo P and Hogstrand C, 2017. Scientific opinion on the assessment of a decontamination process for dioxins and dioxin-like PCBs in fish oil by physical filtration with activated carbon. *EFSA Journal* 2017;15(7): 4961, 10 pp. <https://doi.org/10.2903/j.efsa.2017.4961>

ISSN: 1831-4732

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed¹ provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I of that Directive is prohibited.

Directive 2002/32/EC provides also that Member States are to ensure that measures are taken to guarantee the correct application of any acceptable detoxification process on products intended for animal feed and the conformity of those detoxified products with the provisions of Annex I of that Directive. In order to ensure a uniform assessment across the European Union (EU) of the acceptability of detoxification processes, acceptability criteria for detoxification processes have been established at Union level by Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification processes applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council.

The acceptability criteria for detoxification processes established by the Regulation shall ensure that the detoxified feed does not endanger animal and public health and the environment and that the characteristics of the feed are not adversely altered by the detoxification process. The Regulation furthermore provides that the compliance of a detoxification process with those criteria shall be scientifically assessed by the European Food Safety Authority (EFSA) on a request from the Commission.

The Commission has received the following application referring to a detoxification process for assessment by EFSA of compliance with the acceptability criteria:

| Feed to be decontaminated | Process | Contaminants of concern |
|---------------------------|---|-------------------------|
| Fish oil | Physical filtration with activated carbon | Dioxins and DL-PCBs |

1.1.2. Terms of Reference

In accordance with Art. 29 (1) of Regulation (EC) No 178/2002, the European Commission asks EFSA for an assessment of this detoxification process for compliance with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

1.2. Interpretation of the Terms of Reference

EFSA received from the European Commission requests for scientific opinions on the assessment of applications referring to feed detoxification processes to be compliant with acceptability criteria specified in the Commission Regulation (EU) 2015/786 of 19 May 2015.² In this context, the term detoxification is interpreted as either decontamination by removing the contaminants or by chemical or biological processes able to reduce the toxicity of the contaminants present. This scientific opinion assesses the decontamination process using adsorption with activated carbon and physical filtration of fish oil in order to reduce the amount of dioxins (polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)) and dioxin-like polychlorinated biphenyls (DL-PCBs). The Panel noted that no evidence has been provided on the removal of non-DL-PCBs.

The EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) concluded that the Terms of Reference provided by the European Commission were clear and that the opinion for the assessment of this physical decontamination process should mainly focus on data in order to:

- enable the assessment of the efficacy of the process to remove the contaminants from the feed batches to ensure compliance with the requirements of Directive 2002/32/EC, and

¹ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002.

² Commission Regulation (EU) 2015/786 of 19 May 2015 defining acceptability criteria for detoxification process applied to products intended for animal feed as provided for in Directive 2002/32/EC of the European Parliament and of the Council. OJ L 125/10, 21.5.2015.

- demonstrate that the decontamination process does not adversely affect the characteristics and the nature of the feed.

Information concerning the safe disposal of the removed part of the feed was also considered.

1.3. Additional information

The feed business operator has provided the European Commission with information referring to the proposed decontamination process and its effectiveness as laid down in Directive 2002/32/EC.

2. Data and methodologies

2.1. Data

The feed business operator has submitted information in support to its claim about the efficacy of the decontamination process consisting in the adsorption with activated carbon and physical filtration of fish oil to lower the amount of dioxins and specifically PCDD/Fs and DL-PCBs. This set of documents included information on the decontamination process, on filters, substances and equipment used for the physical decontamination procedures, on analytical data (certificates of analysis), on the Hazard Analysis Critical Control Point (HACCP) procedure and on safe disposal of undesirable substances and materials.

The CONTAM Panel based its assessment exclusively on the information provided (see Section 'Documentation provided to EFSA') to address the Terms of Reference.

2.2. Methodologies

The CONTAM Panel evaluated the acceptability of the proposed decontamination process as requested by the relevant regulations, specifically Directive 2002/32/EC and Commission Regulation (EU) 2015/786 with their Annexes. No similar assessments have been performed in the past by EFSA scientific Panels since according to Art. 8 of the Directive 2002/32/EC the definition of acceptability criteria for detoxification processes and their correct application were under the responsibility of the European Commission and its Committees and the involved Member States. Any assessment is conducted in line with the principles described in the EFSA guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and following the relevant existing guidance from the EFSA Scientific Committee, as appropriate.

3. Assessment

3.1. Method of analysis

The feed business operator has submitted information on the analysis performed by an accredited laboratory (specifically the 'Institut für Veterinär-Pharmakologie und Toxikologie GmbH', Bernau bei Berlin, Germany) with the objective of the analysis being PCDD/F and DL-PCB levels.

The analytical laboratory in carrying out its analytical work has followed provisions of Commission Regulation (EU) No 709/2014 of 20 June 2014 amending Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls³.

3.2. Decontamination process

The feed business operator has submitted sufficient information to assess the operation, including data on PCDD/Fs and DL-PCBs, and a scheme describing the decontamination process of the fish oil, with reference to published literature.

The possibility of removing PCDD/Fs and DL-PCBs through adsorption on activated carbon from liquid media is well known and evidence is available in literature (Epe et al., 2005; Maes et al., 2005; Oterhals et al., 2007). The effectiveness of the procedure may vary depending on different factors such as the medium to be decontaminated, the impurity and its composition and the use of specific activated carbon.

³ Commission Regulation (EU) No 709/2014 of 20 June 2014 amending Regulation (EC) No 152/2009 as regards the determination of the levels of dioxins and polychlorinated biphenyls. OJ L 188, 27.6.2014, p. 1–18.

According to the literature, the adsorption of PCDD/Fs onto activated carbon is highly effective, being able to reduce the levels by up to approximately 95%. The elimination of the DL-PCBs is less effective (depending specifically on the ortho-substitution and the planarity of the molecule) with an approximate level of decontamination of typically about 55%.

3.2.1. Description of the process

A two-step process was described to ensure sufficient removal of unwanted substances while at the same time avoiding residuals of activated carbon in the final detoxified product (Figure 1). The fish oil to be treated was passed through a DESOTEC activated carbon filter tank (MOBICON[®] 2000). The activated carbon used in the tank is currently type ORGANOSORB[®] 10-AA.

The oil then passes from the activated carbon filter to an EATON fabric filter to remove particulates. This may be described as a 'police filter', whose only task is to keep residues of the activated carbon out of the product.

Technical sheets with the characteristics of the activated carbon used and the filters in the treatment of feed commodities intended for the decontamination process were submitted.

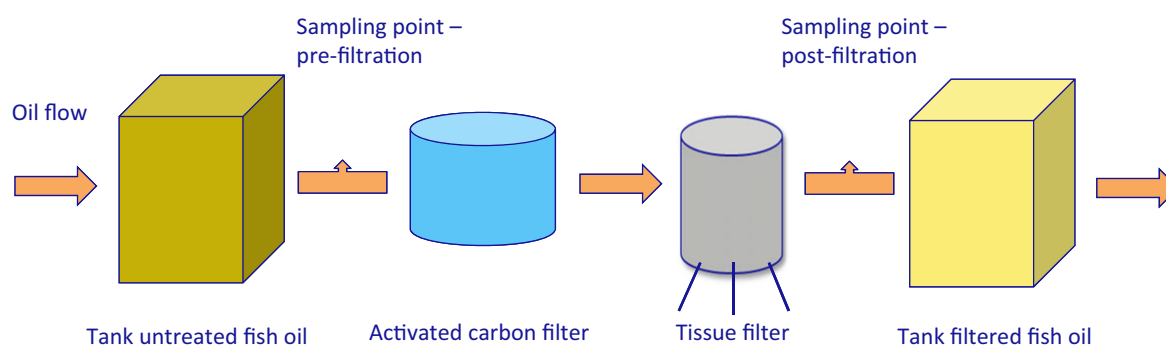


Figure 1: Schematic diagram of the process used by the feed business operator

An authorisation from the national authority (Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei Mecklenburg-Vorpommern) for the establishment to carry out the decontamination process dated June 2016 was provided.

3.2.2. Efficacy of the process

The feed business operator has provided analytical records referring to a total of 35 batches of fish oil that underwent the decontamination process and for which laboratory analysis were performed during the first quarter of 2016. Levels of PCDD/F and DL-PCB for each fish oil sample were measured. Average data from these batches with standard deviation and calculated reduction are reported in Table 1, while the full set of data is in Appendix A.

Table 1: Levels of PCDD/F and DL-PCB in the samples of fish oil before and after the decontamination process

| Total of 35 batches | | | | |
|---------------------|----------------|---------------|--------------------|------------------------|
| | Before process | After process | Mean reduction (%) | Range of reduction (%) |
| PCDD/Fs | 8.88 (2.88) | 1.42 (1.01) | 84 | 49.3–97.7 |
| DL-PCBs | 10.82 (2.16) | 4.92 (1.79) | 55 | 21.0–89.0 |
| Sum of above | 19.71 (4.78) | 6.35 (2.66) | 68 | 35.2–91.8 |

PCDD/Fs: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; DL-PCBs: Dioxin-like polychlorinated biphenyls. Average values; () standard deviation; expressed in ng WHO₂₀₀₅-TEQ/kg.

Data from the 35 batches showed that the decontamination process decreased the sum of the concentration of PCDD/Fs and PCBs (ng WHO₂₀₀₅-TEQ/kg, expressed as 'TCDD toxic equivalent') by approximately 68% and specifically for PCDD/Fs by 84%.

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed and its updates sets action thresholds and maximum limits. Thresholds of

action are needed in order to keep the presence of specific undesirable substances in products intended for animal feed as low as possible in order to reduce their presence in the food chain. Where such action thresholds are exceeded, investigations must be carried out to identify the sources of the undesirable substances and steps taken to reduce or eliminate such sources. As shown in Table 2, the action threshold in fish oil for dioxins (sum of PCDDs and PCDFs) is 4.0 ng WHO₂₀₀₅-TEQ/kg and the maximum level is 5.0 ng WHO₂₀₀₅-TEQ/kg. For DL-PCBs, the action threshold in fish oil is 11.0 ng WHO₂₀₀₅-TEQ/kg while the maximum limit for the sum of PCDD/Fs and DL-PCBs is 20.0 ng/kg.

Table 2: Action thresholds and maximum levels for PCDD/Fs and DL-PCBs in fish oil according to Directive 2002/32/EC and its amendments

| | Action thresholds | Maximum levels |
|---------------------|-------------------|----------------|
| PCDD/Fs | 4.0 | 5.0 |
| DL-PCBs | 11 | – |
| Sum of above | – | 20 |

PCDD/Fs: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans; DL-PCBs: Dioxin-like polychlorinated biphenyls. Expressed in ng WHO₂₀₀₅-TEQ/kg, moisture content of 12%; – not set in regulation.

3.3. Characteristics and nature of the fish oil

Characteristics and nature of the fish oil from decontaminated batches were not described. Therefore, a direct comparison of the same batches before and after the decontamination by means of evaluation of the fatty acids profile and other key characteristics was not feasible.

However, the feed operator made reference to available literature where among the aforementioned papers, Maes et al. (2005) have reported data for this specific aspect. Under the conditions tested there for the decontamination of cod liver oil, no significant effects were found on oil quality and composition with regard to fatty acids. The tests by Oterhals et al. (2007) further confirmed these findings.

The CONTAM Panel was of the view that the information from the relevant literature can be considered valid for the proposed decontamination process and that the use of activated carbon adsorption does not lead to any significant changes in the quality of the fish oil through decontamination; however, it is possible that the process could deplete some beneficial constituents (e.g. vitamins).

3.4. Disposal of the removed materials and filters

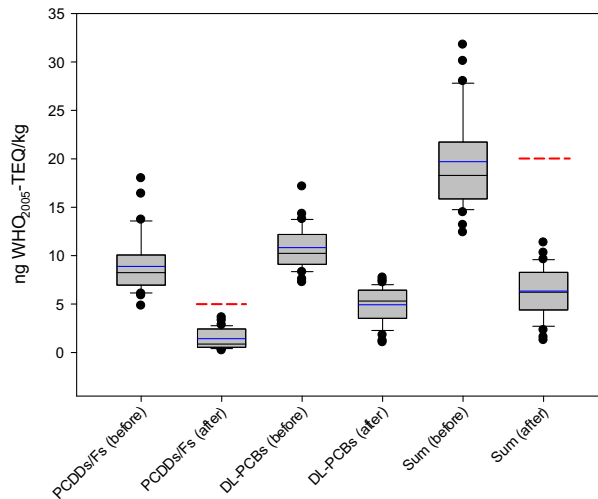
The feed business operator submitted information to demonstrate safe disposal of the waste material. Specifically, a contract for disposal of exhausted filters detailing how the DESOTEC filters are exchanged by the supplier has been provided. As soon as the working life of the filter is reached, the activated carbon contained in the filter is replaced by documented procedure.

3.5. Discussion

The CONTAM Panel assessed the information made available in the documents submitted by the feed business operator and was of the view that sufficient information to make an assessment of the proposed decontamination process for dioxins and DL-PCBs from the fish oil was available.

A short description of the process with its filtration steps was provided, and also some reference to specific literature was made. The Panel also considered that a good general knowledge for this procedure exists and was of the view that a clear picture of the proposed process and its performances was available.

The available data enabled the CONTAM Panel to assess the quality of the analysis performed and to evaluate the efficacy of the decontamination process. In agreement with the literature, the process was more efficient in removing PCDD/Fs (84%) than DL-PCBs (55%). This equated to 68% when considering the two fractions combined. The amount of undesirable substances still in the feed after the decontamination process complied with the levels reported in the Annex I of Directive 2002/32/EC, falling below the legal limits including the action thresholds (Figure 2).



Black lines in box plots show the median and blue lines the arithmetic mean. Whiskers show 10th and 90th percentiles and the dots outliers. Red dashed lines indicate maximum limits in fish oil according to Directive 2002/32/EC and its amendments

Figure 2: Graph representing analytical data from the tested fish oil batches

The CONTAM Panel concluded that it is possible to meet the current EU requirements for quality of fish oil with respect to these contaminants after filtration and adsorption using activated carbon. This assessment is based on the assumption that the levels of dioxins and DL-PCBs in untreated fish oil would be within the range of the batches tested as listed in Appendix A.

Although no experimental evidence was available for the maintained characteristics of the treated fish oil, the Panel considered acceptable the reference to information available in published literature demonstrating the absence of significant changes in fish oil composition characteristics after filtration with activated carbon.

The feed business operator already holds an authorisation from the qualified national authority for the plant to carry out the decontamination processes according to the described method. It is also stated that the exhausted filters are properly replaced.

The CONTAM Panel noted that it is the responsibility of the Member State to ensure that measures are taken to guarantee the correct application of any acceptable decontamination process on products intended for animal feed and the conformity of those decontaminated products with the provisions included in the Commission Regulation (EU) 2015/786 and its Annexes.

3.6. Uncertainty analysis

According to the interpretation of the Terms of Reference, the assessment of a physical decontamination process should mainly focus on the evaluation of the efficacy of the process to remove the contaminants and on the evidence that the characteristics and the nature of the product are not adversely affected.

Efficacy of the process: The method used is based on a well-established process that has been described in the scientific literature. There is little uncertainty in the fact that the process will be effective in removing certain contaminants from the product; however, the specific composition of the starting material will influence the efficacy of the process. There are some remaining uncertainties that may arise from the operation of the process, such as the regularity needed to change the filter. These factors may be checked by regular monitoring of the finished product.

Characteristics of the product: The nutritional characteristics of the treated oil are based on literature information alone and there is therefore some uncertainty as to whether this can be extended to the process under assessment. While it is possible that the process could remove some beneficial constituents (e.g. vitamins), there is little chance that hazardous substances are introduced.

4. Conclusions

In relation to the Terms of Reference, the CONTAM Panel concluded:

- on the basis of the information submitted by the feed business operator the proposed decontamination process is effective in reducing dioxins (PCDD/Fs) and DL-PCBs in the fish oil by means of physical filtration with activated carbon
- the use of activated carbon adsorption does not lead to any detrimental changes in the nature of the fish oil through decontamination, however, it is possible that the process could deplete some beneficial constituents (e.g. vitamins)
- the proposed decontamination process to remove dioxins (PCDD/Fs) and DL-PCBs from the fish oil, was assessed to be compliant with the acceptability criteria provided for in Commission Regulation (EU) 2015/786 of 19 May 2015.

Documentation provided to EFSA

Information provided by Euro Baltic Fischverarbeitungs GmbH in support to the effectiveness of a detoxification procedure using physical filtration to remove unwanted substances from fish oil; June 2016.

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Abbreviations

| | |
|--------------|--|
| CONTAM Panel | EFSA Panel on Contaminants in the Food Chain |
| DL-PCBs | dioxin-like polychlorinated biphenyls |
| HACCP | Hazard Analysis Critical Control Point |
| PCBs | polychlorinated biphenyls |
| PCDDs | polychlorinated dibenzo- <i>p</i> -dioxins |
| PCDD/Fs | polychlorinated dibenzo- <i>p</i> -dioxins and polychlorinated dibenzofurans |
| PCDFs | polychlorinated dibenzofurans |
| TCDD | tetrachlorodibenzo- <i>p</i> -dioxin |
| TEQ | TCDD Toxic equivalent |
| WHO | World Health Organization |

Appendix A – Data analysis for feed batches: before and after decontamination process

| Batch | Dioxins (PCDD/Fs) | | DL-PCBs | | SUM (PCDD/Fs + DL-PCBs) | |
|-------|-------------------|-------|---------|-------|-------------------------|-------|
| | Before | After | Before | After | Before | After |
| 1 | 4.83 | 0.52 | 7.58 | 1.79 | 12.41 | 2.31 |
| 2 | 5.9 | 0.38 | 7.26 | 1.21 | 13.16 | 1.59 |
| 3 | 6.08 | 0.22 | 9.5 | 1.05 | 15.58 | 1.27 |
| 4 | 6.96 | 0.87 | 10.08 | 3.52 | 17.04 | 4.39 |
| 5 | 6.18 | 0.83 | 8.3 | 2.93 | 14.48 | 3.76 |
| 6 | 7.44 | 2.71 | 9.1 | 5.3 | 16.54 | 8.01 |
| 7 | 6.68 | 2.3 | 8.79 | 5.37 | 15.47 | 7.67 |
| 8 | 7.22 | 2.43 | 8.51 | 5.72 | 15.73 | 8.15 |
| 9 | 7.98 | 2.1 | 10.12 | 5.87 | 18.1 | 7.97 |
| 10 | 7.13 | 2 | 10.23 | 6.11 | 17.36 | 8.11 |
| 11 | 6.48 | 1.9 | 9.07 | 5.45 | 15.55 | 7.35 |
| 12 | 8.49 | 2.32 | 10.27 | 7.25 | 18.76 | 9.57 |
| 13 | 7.41 | 2.47 | 10.18 | 6.71 | 17.59 | 9.18 |
| 14 | 6.55 | 3.32 | 8.39 | 6.3 | 14.94 | 9.62 |
| 15 | 6.43 | 2.84 | 9.43 | 7.45 | 15.86 | 10.29 |
| 16 | 7.17 | 2.45 | 9.57 | 6.67 | 16.74 | 9.12 |
| 17 | 8 | 3.62 | 10.21 | 7.73 | 18.21 | 11.35 |
| 18 | 7.86 | 2.58 | 9.06 | 6.35 | 16.92 | 8.93 |
| 19 | 8.5 | 2.6 | 10.54 | 6.83 | 19.04 | 9.43 |
| 20 | 8.58 | 0.68 | 12.27 | 4.33 | 20.85 | 5.01 |
| 21 | 9.33 | 0.69 | 11.79 | 4.23 | 21.12 | 4.92 |
| 22 | 17.99 | 0.42 | 13.79 | 4.15 | 31.78 | 4.57 |
| 23 | 10.07 | 0.53 | 11.56 | 3.36 | 21.63 | 3.89 |
| 24 | 10.09 | 0.48 | 13.18 | 4.01 | 23.27 | 4.49 |
| 25 | 10.37 | 0.41 | 13.71 | 4.45 | 24.08 | 4.86 |
| 26 | 8.25 | 0.58 | 10.04 | 4.72 | 18.29 | 5.3 |
| 27 | 16.41 | 0.34 | 13.69 | 2.64 | 30.1 | 2.98 |
| 28 | 11.36 | 0.63 | 11.85 | 4.37 | 23.21 | 5 |
| 29 | 9.55 | 1.59 | 11.76 | 6.68 | 21.31 | 8.27 |
| 30 | 8.73 | 1.34 | 10.86 | 6.43 | 19.59 | 7.77 |
| 31 | 9.56 | 1.12 | 12.18 | 4.98 | 21.74 | 6.1 |
| 32 | 9.52 | 0.49 | 11.19 | 2.6 | 20.71 | 3.09 |
| 33 | 10.53 | 0.53 | 17.14 | 3.41 | 27.67 | 3.94 |
| 34 | 13.51 | 0.78 | 13.35 | 5.44 | 26.86 | 6.22 |
| 35 | 13.72 | 0.8 | 14.31 | 6.83 | 28.03 | 7.63 |
| Mean | 8.88 | 1.42 | 10.82 | 4.92 | 19.71 | 6.35 |
| SD | 2.88 | 1.01 | 2.16 | 1.79 | 4.78 | 2.66 |